UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ACTOS ANTITRUST LITIGATION THIS DOCUMENT RELATES TO: ALL ACTIONS	Master File No. 1:13-cv-09244-RA-SDA SEALED VERSION

PLAINTIFFS' LETTER MOTION FOR DISCOVERY CONFERENCE REGARDING DOCUMENTS SUBJECT TO TAKEDA'S PRIVILEGE WAIVER

Plaintiffs request a discovery conference to seek an order clarifying that the scope of Takeda's privilege waiver encompasses all evidence relevant to its good faith regulatory compliance defense. This includes, but is not limited to, all otherwise-privileged documents and communications showing (a) Takeda's reasons (*all of them*) for engaging in the alleged restraint, *i.e.*, the wrongful listing of patents in FDA's "Orange Book" and the maintenance of those listings between 1999 and 2012, (b) Takeda's assessment of whether those listings and the maintenance thereof comported with ongoing statutory or regulatory obligations between 1999 and 2012, and (c) Takeda's consideration between 1999 and 2012 of the consequences of those improper listings, including on generic entry. Takeda cannot have its cake and eat it, too. If Takeda wishes to carve out any of these documents from its waiver—thereby denying Plaintiffs the opportunity to test its good faith compliance defense—Takeda should be precluded from asserting the defense at trial. Plaintiffs further request that the Court compel Takeda to produce, by September 23rd, all documents subject to the waiver, including the categories highlighted below. A proposed order is attached hereto as Exhibit H.

Background

This antitrust action concerns Takeda's scheme to delay generic competition for its drug Actos (pioglitazone). In 1999 and 2002, Takeda falsely described two patents (the '584 and '404) as claiming Actos in submissions to FDA. Takeda reaffirmed those descriptions for over a decade, forcing generic competitors to address the patents in their FDA applications using Paragraph IV certifications instead of section viii statements. These certifications triggered regulatory barriers that delayed generic entry for two years beyond January 2011, when Takeda's patent that lawfully claimed Actos (the '777) expired.

The Second Circuit has held that Takeda's patent characterizations were wrong.[1] As an affirmative defense, Takeda asserts that it acted in "good faith" to comply with regulatory mandates.[2] This defense entails an objective element ("reasonableness") and a subjective one (good faith belief).[3] On April 22, 2022, Takeda informed Plaintiffs it would rely on privileged documents to support the defense. Ex. A at 1. Takeda later produced a tranche of documents subject to the waiver, many of which were redacted. On May 6 and May 20, Takeda produced defective categorical privilege logs covering 10,501 documents. Ex. B. Many categories included hundreds or even thousands of documents, with date ranges spanning 10 years or more, and pertained to topics relevant to Takeda's beliefs about its alleged misconduct. Ex. A at 3-6. Takeda later produced a partial metadata log (which included information such as dates, e-mail subject lines, document titles, and to/from/cc fields) containing 4,543 entries. Ex. C. This log further confirmed that Takeda had withheld thousands of documents subject to the waiver.

On August 12, Plaintiffs provided Takeda with examples of inappropriate withholdings. *See* Ex. A at 11-15. On August 22, the parties held a meet-and-confer regarding Takeda's bases for withholding certain categories of documents. Ex. A at 19-20 (Plaintiffs' Questions to Takeda). It was clear from the call that the parties were at an impasse.[4] Plaintiffs' view, based on Second Circuit precedent, is that the scope of Takeda's waiver encompasses all documents relevant to its affirmative defense—*i.e.*, all evidence of Takeda's "state of mind" with respect to the challenged misconduct, including its actual motives or intent. Takeda believes it can more narrowly define its waiver, and that the only documents relevant to its defense (and subject to waiver) are those pertaining to the specific subject matter articulated in its April 22 letter—namely, "[t]he applicability of the pre-2003 regulations governing the submission of patent information to FDA (21 C.F.R. § 314.53) for U.S. Patent Nos. 5,965,584 and 6,329,404 in connection with ACTOS, and Takeda's compliance with those pre-2003 regulations." Ex. A at 1.

Legal Standard

[1] *United Food & Commer. Workers Local 1776 v. Takeda Pharm. Co.*, 11 F.4th 118, 136 (2d Cir. 2021).

[2] *See* Defs.' Answer to EPP's Fourth Consol. Compl., ECF No. 279 (Oct. 22, 2019). On August 22, 2022, Takeda's counsel confirmed that its defense applies to all alleged misconduct, including the wrongful 1999 and 2002 patent listings.

[3] *See, e.g.*, *In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 13 (1st Cir. 2020) (discussing elements of the defense).

[4] This conference took place from 3-4 PM. Natasha Fernández-Silber and Matthew Weiner participated for Plaintiffs, and Patrick Huyett and Melina DiMattio for Defendants. Defendants agreed to motion practice.

The scope of a party's privilege waiver is defined by two related fairness principles. *First*, under Federal Rule of Evidence 502, a party that waives privilege as to certain information must disclose all *other* information that "concern[s] the same subject matter" and that "ought in fairness be considered together." This rule stems from the tenet that "the attorney-client privilege cannot at once be used as a shield and a sword. A defendant may not use the privilege to prejudice his opponent's case or to disclose some selected communications for self-serving purposes."[5] *Second*, where a party asserts a defense such as good faith compliance, it puts at issue its "state of mind" with respect to its misconduct, resulting in an implied waiver as to all evidence thereof.[6] The scope of such waiver is broad,[7] applying to all documents relevant to the defense.[8] Applying these principles, courts have deemed a wide range of materials subject to a party's implied waiver, including documents reflecting a party's "knowledge of the law and the basis for . . . [its] understanding of what the law required," including "conversations with counsel";[9] legal advice and opinions that a party rejected;[10] evidence of motive and intent exposing as false or pretextual purported good faith justifications;[11] and uncommunicated attorney work product.[12]

Relief Requested

Takeda purports to waive privilege only as to the "applicability" of "pre-2003 regulations." Takeda cannot limit its waiver in this way while asserting a good faith compliance defense. Plaintiffs request that the Court clarify that the scope of Takeda's waiver includes all documents relevant to its affirmative defense.[13] This includes otherwise-privileged materials showing Takeda's patent descriptions may have been motivated by business concerns (such as generic suppression) or reflecting Takeda's ongoing assessment of regulatory mandates. Takeda may not "divulge only those documents . . . favorable to [its] defense," while depriving Plaintiffs (and the jury) of meaningful context, and of

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[5] *United States v. Bilzerian*, 926 F.2d 1285, 1292 (2d Cir. 1991) (citations omitted).

[6] *See, e.g.*, *id.* at 1292-94 ("privilege may implicitly be waived when defendant asserts a claim that in fairness requires examination of protected communications") (citing *United States v. Exxon Corp.*, 94 F.R.D. 246, 249 (D.D.C. 1981)); *In re Cty. of Erie*, 546 F.3d 222 at 228-29 (2d Cir. 2008) ("[T]he assertion of a good-faith defense involves an inquiry into state of mind, which typically calls forth the possibility of implied waiver of the attorney-client privilege."). Such implied waiver occurs even where a party does not explicitly claim to rely on privileged documents. *Leviton v. Greenberg Traurig*, No. 9-8083, 2010 WL 4983183, at *3 (S.D.N.Y. Dec. 6, 2010) ("[A] party need not explicitly rely upon advice of counsel to implicate privileged communications. [A]dvice of counsel may be placed in issue where . . . a party's state of mind, such as his good faith belief in the lawfulness of his conduct, is relied upon in support of a claim of defense.").

[7] Takeda appears to conflate subject matter waiver with waiver flowing from the assertion of a good faith regulatory compliance defense in order to argue, incorrectly, that the waiver here is "narrow." Ex. A at 1. It is not. Plaintiffs are entitled to all documents concerning Takeda's defense.

[8] *See, e.g.*, *Su v. City of New York.*, No. 06-687, 2007 WL 9719337, at 6* (E.D.N.Y. Sept. 10, 2007) ("Broad waiver allowing full discovery has been found when a party has raised a defense that places the advice of counsel at issue and then seeks to testify about that privileged information at trial.") (citing *Bilzerian*, 926 F.2d at 1292); *U.S. v. Exxon Corp.*, 94 F.R.D. 246 at 249 (where "waiver is generated by the injection of an entire defense . . . . [it] must pertain to all documents bearing upon the subject matter of the defense" because "[o]therwise, the party interposing the defense is free to divulge only those documents that are most favorable to his defense; this is precisely the inequitable result that the waiver doctrine seeks to avoid"); *United States v. Locascio*, 357 F. Supp. 2d 536, 552 (E.D.N.Y. 2004) (in determining scope of waiver resulting from good faith defense, "[the] issue [is] largely one of relevance").

[9] *See, e.g.*, *Bilzerian*, 926 F.2d at 1292.

[10] *See, e.g.*, *Scott v. Chipotle Mexican Grill, Inc.*, 67 F. Supp. 3d 607, 611 (S.D.N.Y. 2014) ("[A]s a matter of fairness, waiver may apply even if the defendant claims to have ignored the advice of counsel . . . .").

[11] *Leviton*, 2010 WL 4983183, at *3 (S.D.N.Y. Dec. 6, 2010) ("Because legal advice that a party received may well demonstrate the falsity of its claim of good faith belief, waiver in these instances arises as a matter of fairness . . . ."); *S. Pac. Commc'ns Co. v. Am. Tel. & Tel. Co.*, 740 F.2d 980, 1009 (D.C. Cir. 1984) (evidence showing attempt to "rationalize a decision whose purpose is anticompetitive" relevant to regulatory compliance defense).

[12] *See, e.g.*, *In re Buspirone Antitrust Litig.*, 208 F.R.D. 516, 524-25 (S.D.N.Y. 2002) (requiring production of uncommunicated work product, noting defendant had in-house counsel, was not fully reliant on advice of outside counsel, and that communications with counsel are rarely in written form).

[13] *Exxon Corp.*, 94 F.R.D. at 249 (where "waiver is generated by the injection of an entire defense, [it] must pertain to all documents bearing upon the subject matter of the defense").

evidence capable of rebutting the reasonableness of its alleged beliefs.[14] Plaintiffs request that Takeda produce (without redaction)[15] documents subject to its waiver (including the below) by September 23rd.

1. Patent Analysis. Takeda claims privilege over documents reflecting its analysis of Actos-related patents, the regulations governing their listing and description, and the consequences of Takeda's listings on generic entry (Categories 3, 15, 16, and 29, described in Takeda's Categorical Logs (Ex. E)). Takeda's metadata log includes documents with names like "Pioglitazone Electronic Orange Book Listing.doc" (TAK-ACTOS_000530080) and e-mails on subjects such as "FDA Letter requesting to review Actos patents in Orange Book" (TAK-ACTOS_000530088). Such evidence is plainly probative of Takeda's defense. Plaintiffs seek production of all documents in Categories 3, 15, 16, and 29.

2. Sandoz Citizen Petition ("CP") & Takeda's 2009/2010 Listing Reaffirmations. In 2009, the generic company Sandoz submitted a Citizen Petition concerning Takeda's patent listings, seeking a ruling from FDA requiring all prospective generics manufacturers to address the '404 and '584 patents with Paragraph IV certifications. FDA granted that petition in 2010, based on Takeda's wrongful patent submissions, which Takeda confirmed to FDA via correspondence in 2009 and public comment in 2010. In 2010, Teva then challenged the accuracy of the listings under 21 CFR 314.53(f), triggering FDA to request that Takeda confirm or correct its listing information. Takeda represented that its patent descriptions were correct. Takeda claims privilege over documents concerning the Sandoz CP (Category 35) and Teva's 21 CFR 314.53(f) challenge (Category 29). These documents are highly likely to reflect Takeda's state of mind with the respect to the challenged listings and Takeda's ongoing strategy for defending those listings. Takeda has selectively disclosed some of these documents, a misuse of privilege as both a sword and a shield.[16] Plaintiffs seek production of all documents concerning the Sandoz CP, Teva's subsequent challenge, and Takeda's responses, including those in Category 35 and 29.

3. Patent Litigation. Takeda engaged in patent litigation with prospective generic Actos manufacturers from 2003 until 2011. Takeda has withheld documents from these litigations (Categories 1, 2, and 4). Because the patent litigations stemmed from and put at issue Takeda's wrongful listings, documents from these proceedings are likely to be probative of Takeda's state of mind with respect to the alleged restraint. Plaintiffs seek production of all documents from Categories 1, 2, and 4 relevant to Takeda's affirmative defense, including those reflecting Takeda's assessment of (a) which infringement claims to assert or maintain, or (b) any counterclaim putting at issue the propriety of Takeda's listings.

4. Settlement Strategy/Negotiations. Takeda has withheld documents related to the settlement of the patent litigations (Category 5). Settlement-related documents are likely to reveal Takeda's views on the strength of its patents and its motivations for reaffirming its wrongful listings in 2009 and 2010.[17] Takeda has disclosed some of these documents, using privilege as both a sword and a shield.[18] Plaintiffs seek all documents concerning settlement strategy and negotiations, including those in Category 5.

5. Hogan Lovells Retention.[19] Takeda retained the firm Hogan Lovells ("HL") in 2009 to advise on regulatory issues, including "whether the composition claims in the '404 and '584 patents can be said to claim the single entity Actos product, for purposes of the FDA patent listing regime." Ex. G (TAK-ACTOS_000519220). Plaintiffs seek all HL documents relevant to Takeda's affirmative defense, including those probative of Takeda's motivations for reaffirming its wrongful listings in 2009 and 2010.

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[14] *See id.* at 249.

[15] Takeda has heavily redacted numerous documents it produced pursuant to the waiver. *See* Ex. D (*E.g.*, TAK-ACTOS_000529984). This is impermissible under F.R.E. 502, which extends a party's waiver to all information "concerning the same subject matter" as disclosed information.

[16] Ex. F at 1, TAK-ACTOS_000513468 (Nov. 2009 email from attorney B. McCormick advising Takeda on Sandoz CP), attaching TAK-ACTOS_000513470 ("Outline of Arguments in Opposition to Teva Comment on Sandoz [CP]").

[17] Takeda's 2009/2010 reaffirmations occurred during the settlement discussions and were apparently motivated by "the importance of [the Sandoz CP]" to Takeda's "settlement strategy." Ex. F at 1 (TAK-ACTOS_000513468).

[18] Ex. F at 7, 9, TAK-ACTOS_000527117; TAK-ACTOS_000527129 (redacted July 2009 emails regarding settlement).

[19] Takeda has collected documents from Hogan Lovells but has yet to produce them. Takeda maintains that the HL documents Plaintiffs seek will be withheld for privilege, including the retention letter for the representation at issue.

Dated: August 30, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Thomas M. Sobol, certify that, on this date, the foregoing document was filed electronically via the Court's CM/ECF system, which will send notice of the filing to all counsel of record, and parties may access the filing through the Court's system.

Dated: August 30, 2022

/s/ Thomas M. Sobol
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